c.) Amendments to the Claims

Claims 1-14 (Cancelled).

15. (Currently Amended) An intrabuccally rapidly disintegrating tablet ~~made of~~ comprising compressed granulated materials ~~which are made by~~ produced according to the steps comprising:

selecting an aqueous solution comprising a binder and a saccharide with high wettability against water,

~~(I) combining (a)~~ granulating a powdered mixture ~~including at least~~ comprising ~~a main ingredient~~ an active agent, a saccharide with high wettability against water and a disintegrant ~~with (b)a binder containing therein~~ using said aqueous solution to make a granulated material,

~~wherein said saccharide with high wettability against water has a kinetic viscosity less than or equal to 0.92cm stoke in a density of 10.g/100ml, and~~

~~(ii)~~drying the granulated material, and

compressing the dried granulated material ~~materials without their surface being moistened~~.

16. (Currently Amended) An intrabuccally rapidly disintegrating tablet ~~made of~~ comprising compressed granulated materials ~~which are made by~~ produced according to the steps comprising:

selecting an aqueous solution comprising a binder and a saccharide with high wettability against water,

~~(I) combining (a)~~ granulating a powdered mixture ~~including at least~~

comprising ~~a main ingredient~~ an active agent, a saccharide with high wettability against water, a saccharide with high moldability and a disintegrant ~~with (b) a binder containing therein~~ using said aqueous solution ~~a saccharide with high wettability against water~~ to make a granulated material,

~~wherein said saccharide with high wettability against water has a kinetic viscosity less than or equal to 0.92cm stoke in a density of 10.g/100ml, and~~

~~(ii)~~drying the granulated material, and

compressing the dried granulated material ~~without their surface being moistened~~.

17. (Previously Presented) The tablet as set forth in claim 16, wherein the volume ratio in said granulated materials of said saccharide with high wettability against water to said saccharide with high moldability is within the range of 6:4 to 9:1.

18. (Currently Amended) The tablet as set forth in claim 16 or 17, wherein both of said ~~saccharide~~ saccharides with high ~~moldability is~~ wettability are selected from the group consisting of lactose, maltitol, sorbitol, and oligosaccharide.

19. (Previously Presented) The tablet as set forth in any one of claims 15 to 17, wherein both of said ~~saccharide~~ saccharides with high wettability against water ~~is~~ are selected from the group consisting of trehalose, mannitol, maltose, sorbitol, lactose, multitol, xylitol, sucrose, erythritol, and glucose.

20. (Currently Amended) The tablet as set forth in any one of claims 15 to 17, wherein said aqueous solution further contains a surface active agent ~~is further~~

~~contained in said binder~~.

21. (Currently Amended) A method of producing an intrabuccally rapidly disintegrating tablet comprising the steps of:

homogeneously fluidizing with air powdered mixtures ~~including at least~~ comprising ~~a main ingredient~~ an active agent, a saccharide with high wettability against water and a disintegrant, ~~said saccharide with high wettability against water has a kinetic viscosity less than or equal to 0.92cm stoke in a density of 10.g/100ml~~

selecting ~~producing granulated materials by spraying~~ an aqueous solution ~~containing therein~~ comprising a binder and a ~~said~~ saccharide with high wettability against water;

spraying said aqueous solution into said powdered mixtures and subsequently drying said powdered mixtures to obtain granulated materials; and

compressing said granulated materials thus produced ~~without their surface being moistened~~.

22. (Currently amended) A method of producing an intrabuccally rapidly disintegrating tablet comprising the steps of:

homogeneously fluidizing with air powdered mixtures ~~including at least~~ comprising ~~a main ingredient~~ an active agent, a saccharide with high wettability against water, a saccharide with high moldability and a disintegrant, ~~said saccharide with high wettability against water has a kinetic viscosity less than or equal to 0.92cm stoke in a density of 10.g/100ml~~.

selecting ~~producing granulated materials by spraying~~ an aqueous solution ~~containing therein~~ comprising a binder and a ~~said~~ saccharide with high wettability

against water;

spraying said aqueous solution into said powdered mixtures and subsequently drying said powdered mixtures to obtain granulated materials; and

compressing said granulated materials thus produced ~~without their surface being moistened~~.

23. (Currently amended) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in ~~claim 21 or 22~~ any one of claims 21, 22 or 30, wherein said aqueous solution further contains a surface active agent ~~is further contained in said binder~~.

24. (Currently Amended). The method for producing an intrabuccally rapidly disintegrating tablet as set forth in ~~claims 21 or 22~~ any one of claims 21, 22 or 30, wherein the volume of the binder contained in said aqueous solution is greater than or equal to 1 volume, and less than or equal to 3 volumes, per 100 volumes of said aqueous solution ~~water~~ and the volume of said saccharide with high wettability against water contained in said aqueous solution is greater than or equal to 5 volumes, and less than or equal to 6 volumes, per 100 volumes of said aqueous solution ~~water~~.

25. (Currently Amended). The method for producing an intrabuccally rapidly disintegrating tablet as set forth in claim 23, wherein the volume of the binder contained in said aqueous solution is greater than or equal to 1 volume, and less than or equal to 3 volumes, per 100 volumes of said aqueous solution ~~water~~ and the volume of said saccharide with high wettability against water contained in said aqueous solution is greater than or equal to 5 volumes, and less than or equal to 6 volumes, per 100 volumes of said

aqueous solution ~~water~~.

26. (New) The tablet as set forth in any one of claims 15 to 17, wherein said binder is a water-soluble polymer.

27. (New) The tablet as set forth in claim 26, wherein said water-soluble polymer is selected from the group consisting of hydroxypropylcellulose and polyvinyl alcohol.

28. (New) The tablet as set forth in any one of claims 15 to 17, wherein said disintegrant is selected from the group consisting of crospovidone, croscarmellose sodium, and low substituted hydroxypropylcellulose.

29. (New) The tablet as set forth in any one of claims 15 to 17, wherein the volume of the binder contained in said aqueous solution is greater than or equal to 1 volume, and less than or equal to 3 volumes, per 100 volumes of said aqueous solution and the volume of said saccharide with high wettability against water contained in said aqueous solution is greater than or equal to 5 volumes, and less than or equal to 6 volumes, per 100 volumes of said aqueous solution.

30. (New) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in claim 22, wherein the volume ratio in said granulated materials of said saccharide with high wettability against water to said saccharide with high moldability is within the range of 6:4 to 9:1.

31. (New) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in claim 22 or 30, wherein said saccharide with high moldability is selected from the group consisting of lactose, maltitol, sorbitol, and oligosaccharide.

32. (New) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in any one of claims 21, 22 or 30, wherein said saccharide with high wettability against water is selected from the group consisting of trehalose, mannitol, maltose, sorbitol, lactose, multitol, xylitol, sucrose, erythritol, and glucose.

33. (New) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in any one of claims 21, 22 or 30, wherein said binder is a water-soluble polymer.

34. (New) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in 33, wherein said water-soluble polymer is selected from the group consisting of hydroxypropylcellulose and polyvinyl alcohol.

35. (New) The method for producing an intrabuccally rapidly disintegrating tablet as set forth in any one of claims 21, 22 or 30, wherein said disintegrant is selected from the group consisting of crospovidone, croscarmellose sodium, and low substituted hydroxypropylcellulose.

c.) Remarks

The claims have been amended in order to recite the present invention with the specificity required by statute. Additionally, new claims 26-35 are presented in order to more specifically recite various preferred embodiments of the present invention. No new matter has been added.

The Examiner has objected to the specification for the formal reasons noted. In response, reference to "claims" has been deleted. Accordingly, this rejection is mooted.

Claims 15-25 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the limitation "comprising the granulated materials without their surfaces being moistened" is not found in the specification as filed. Although respectfully traversed, in response, this feature has been cancelled as unnecessary in view of the prior art, and in order to reduce the issues to expedite prosecution.

Claims 15-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mizumoto (EP 0 745 382) in view of Sangekar (US 3,957,662). This rejection is respectfully traversed in view of the foregoing amendment and the following remarks.

As the Examiner will appreciate, the present invention is characterized, in part, (I) that an active agent is mixed with a saccharide having high wettability against water and a disintegrant, and in that (II) such mixture is granulated using an aqueous solution in which a binder and a saccharide with high wettability against water are dissolved. Thereafter the granulated material thus produced is dried and then tabletted. As the result, Applicants have found that the resulting tablet exhibits superior disintegration as well as good moldability for tabletting with a very practical hardness.

As relied upon in the Office Action, Mizumoto Example 11 shows

granulating a powder mixture containing an active ingredient, lactose and mannitol using aqueous granulation liquid containing mannitol. Mizumoto claim 17 is said to "teach" that the tablets may contain additional materials, such as disintegrant and binder[1/]

By way of context, however, Mizumoto (see page 5, lines 10-13) explicitly teaches that the high moldability saccharide is a binder for granulation. Mizumoto further describes granulation (using a fluidized bed granulator, a vertical mixer, an agitated granulating machine or the like) by mixing active agent with a low moldability saccharide for coating and granulation using the aqueous high moldability saccharide as binding agent. That is, Mizumoto describes once that even if a low moldability saccharide is utilized, after coating, still the material is granulated using a high moldability saccharide (page 9, lines 34-38).

Accordingly, respectfully submitted, the Examiner's reliance of Mizumoto page 9, lines 51-54 as showing use of a solution containing dissolved saccharide with high moldability and additives "as binder for coating and/or granulating" is thus taken out of context and without basis in fact, That is, Mizumoto neither teaches nor suggests granulating (I) a mixture of (i) active agent, (ii) saccharide with high wettability against water and (iii) disintegrant using (II) a solution containing (i) a saccharide with high wettability and (ii) binder.

Nor is this deficiency remedied by the secondary reference. Sangekar, which is relied upon only as showing that tablets containing surface active agent can be easily dispersed and have superior disintegrating ability. However, Sangekar does not teach or suggest a process using a granulation solution containing a binder and a saccharide

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1/ Applicants disagree that such is the necessary "teaching" of features in embodiments to be combined necessary for *prima facie* case of obviousness, but to reduce the issues, are not arguing on this basis.

with high wettability against water of the pending claims over the prior art.

Accordingly, there is no *prima facie* obviousness of the pending claims over the prior art.

Nonetheless, solely in order to still further reduce the issues and better expedite prosecution herein, Applicants have conducted experiments in order to illustrate the unexpected superiority of the present invention over the closest prior art. Those experiments are now completed and are presented in the accompanying Declaration under Rule 132.

As will be appreciated from the Declaration, Example 1 shows the disintegration time and tablet hardness obtained from the present invention, e.g., in which a mixture of a saccharide with high wettability against water and a disintegrant is granulated using a solution comprising a binder and a saccharide with high wettability against water, and thereafter drying and tabletting the granulated material.

Comparison 1 is similar but shows the disintegration time and tablet hardness in which a mixture of a saccharide with high wettability against water and a disintegrant is granulated using such a solution containing a saccharide with high wettability against water, but without binder.

Comparison 2 is again similar but shows the disintegration time and tablet hardness in which a mixture of a saccharide with high wettability against water and a disintegrant is granulated by using a solution dissolving therein only a binder, but without a saccharide with high wettability against water.

As illustrated, the tablets obtained by the present invention, e.g., using a solution dissolving therein a binder and a saccharide with high wettability against water, were at least twice as hard than comparative tablets but surprisingly, did not exhibit reduced disintegration time. Plainly, this result is both unexpected and of obvious utility

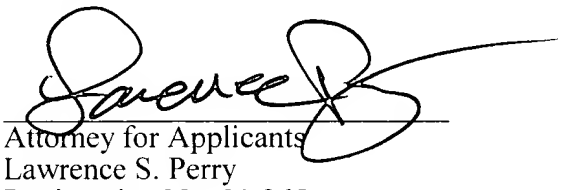
to those of ordinary skill in the art.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 15-35 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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